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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|----------------------|
| 10/650,174 | 08/28/2003 | J. Wallace Parce | 100/06341 | 5968 |
| 21569 | 7590 | 12/12/2007 | EXAMINER | |
| CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234 | | | | GROSS, CHRISTOPHER M |
| ART UNIT | | PAPER NUMBER | | |
| 1639 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 12/12/2007 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|----------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/650,174 | PARCE ET AL. |
| | Examiner | Art Unit |
| | Christopher M. Gross | 1639 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 October 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-21,23-27 and 29 is/are pending in the application.
 - 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-21,23,27,29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Responsive to communications entered 10/1/2007. Claims 1,3-21,23-27,29 are pending. Claims 24-26 are withdrawn. Claims 1,3-21,23,27,29 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C.121 is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The instant application, filed 12/11/2002 is a DIV of 09/579,111 05/25/2000 (now PAT 6,649,358 which claims benefit of 60/155,259 06/01/1999 and claims benefit of 60/176,001 01/12/2000 and claims benefit of 60/176,093 01/14/2000 and claims benefit of 60/191,784 03/24/2000.

Nevertheless, support for the limitation set forth in claim 1 related to detecting a detectable signal that indicates an initial concentration of at least one first component or set of first components prior to entry of the at least one first components or the set of first components into a first channel is not found in the earlier provisional applications. It is further noted that the provisional applications are drawn to methods and devices for detecting transporter activity as opposed to a method of detecting binding activity set forth as the presently claimed subject matter.

Therefore 5/25/2000 is the date for the purposes of prior art concerning claims 1,3-21,23-27,29.

Response to Arguments

Applicant argues, see p 7 (10/1/2007) that priority to all previous applications was granted in the Office Action mailed 11/30/2005. It is noted however, that upon further review, support for the limitations cited above - at minimum - could not be found in applications earlier than 09/579,111 filed 05/25/2000.

If Applicant feels otherwise applicant is required to point out (specified as to page and line) where the earlier application(s) provide support under 35 USC 112 first paragraph for each claimed element.

Withdrawn Objection(s) and/or Rejection(s)

The rejection of Claim 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

Maintained Claim Rejection(s) - 35 USC § 102

Claims 1,3,5,23,27 are rejected under 35 U.S.C. 102(b) as being anticipated by Weigl et al (1999 Science 283:346-347). 1,3-21,23,27,29

Response to Arguments

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

Specifically, applicant argues see p 8-9 (10/1/2007) Weigl et al do not teach "detecting a detectable signal that indicates a final concentration of at least one first component or set of first components that remains unbound after exiting from the first channel, thereby detecting binding activity," as set forth as the last listed step of claim 1. Applicant further contrasts figure 6 of the present application, showing detector element 606 positioned in a secondary channel which detects unbound indicator, as opposed to figure 1 of Weigl et al which shows bound indicator detected in the primary (first) channel.

It is the Examiner's position, however that Weigl et al implicitly teach detecting a detectable signal *that indicates a final concentration* because the unbound species and bound species are related through a stoichiometric relationship: Total Indicator = Bound Indicator + Unbound Indicator, or rearranged Unbound Indicator = Total Indicator - Bound Indicator. And, as mentioned in the last Office Action on p 9, line 3 Weigl et al

measure Total fluorescence at 0 g/ ml human serum albumin (HSA). Using said relationship, "[the amount which] remains unbound after exiting from the first channel" may be detected. Furthermore, it is Examiner's position that *all* indicator ultimately exits the primary channel, whether into a secondary channel or otherwise.

On the other hand, Applicant also argues, see p 9 (10/1/2007) that the detection according to Weigl et al occurs within the primary channel rather than occurring downstream, in a detector located after a branch point (i.e. in a secondary channel).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., detection of unbound indicator occurring beyond the first channel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 1,3,7-15,20-21,23,27,29 are rejected under 35 U.S.C. 102(a) as being anticipated by Kamholz et al (1999 Anal Chem 71:5340-5347) as evidenced by Mastro et al (1984 PNAS 81:3414-3418).

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

Specifically, applicant argues see p 10 (10/1/2007) Kamholz et al do not teach "detecting a detectable signal that indicates a final concentration of at least one first

component or set of first components that remains unbound after exiting from the first channel, thereby detecting binding activity," as set forth as the last listed step of claim 1.

It is the Examiner's position, however that Kamholz et al implicitly teach detecting a detectable signal *that indicates a final concentration* because the unbound species and bound species are related through the stoichiometric relationship: Total Indicator = Bound Indicator + Unbound Indicator, or rearranged Unbound Indicator = Total Indicator - Bound Indicator. And, as mentioned in the last Office Action on p 11, line 5 Kamholz et al measure Total fluorescence at 0 g/ ml human serum albumin (HSA). Using said relationship, "[the amount which] remains unbound after exiting from the first channel" may be detected. Furthermore, it is Examiner's position that *all* indicator ultimately exits the primary channel, whether into a secondary channel or otherwise.

On the other hand, Applicant also argues, see p 10 paragraph 5 (10/1/2007) that the detection according to Kamholz et al occurs within primary channel rather than occurring downstream, located after a branch point in a secondary channel..

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., detection of unbound indicator occurring beyond the first channel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 1,3-21,23,27,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of **Weigl et al** (1999 *Science* 283:346-347) or **Kamholz et al** (1999 *Anal Chem* 71:5340-5347) as evidenced by **Mastro et al** (1984 *PNAS* 81:3414-3418), each taken separately in view of **Suzuki et al** (1999 *JBC* 274:31131-31134).

Response to Arguments

Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 102 rejection. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above sections, which are incorporated in their entireties herein by reference.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

Christopher M. Gross, Ph.D.



MARK L. SHIBUYA
PRIMARY EXAMINER